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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,590	07/30/2007	Richard C. Ebersole	CL2272USPCT	8973
23906 7590 12/08/2009 E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1122B 4417 LANCASTER PIKE WILMINGTON, DE 19805				
EXAMINER CHEN, STACY BROWN				
ART UNIT 1648		PAPER NUMBER		
NOTIFICATION DATE 12/08/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-Legal.PRC@usa.dupont.com

Office Action Summary

Application No.

10/538,590

Applicant(s)

EBERSOLE ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 and 5-8 is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 17, 2009 has been entered. Claims 1-8 remain pending and under examination. The examiner unsuccessfully attempted to contact Applicant's representative by telephone on November 25, 2009 and December 2, 2009, in order to discuss the remaining art rejection.

Response to Amendment

2. The objection to the specification is withdrawn in view of Applicant's amendment.

Claims Summary and Interpretation

3. Note that the subject matter of claim 4, "consisting essentially of SEQ ID NO: 16", for example, is interpreted by the Office to read on any polynucleotide that contains SEQ ID NO: 16, that is capable of being used as a primer for nucleic acid amplification for detection of FMDV. In addition to SEQ ID NO: 16, the sequence may also include other sequences that do not materially affect the basic and novel characteristics of the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 remains rejected under 35 U.S.C. 102(b) as being anticipated by Beard *et al.* (*Journal of Virology*, 2000, 74(2):987-991, "Beard"). Beard's disclosure of the entire genome of the type O FMDV anticipates the instantly claimed polynucleotide because the genome of type O FMDV naturally contains SEQ ID NO: 16-20 (see instant specification, page 11, lines 11-13, and Table 1 on page 12). The isolated nucleotide disclosed by Beard is capable of use in the detection of FMDV because the claim is not limited to any particular detection method that excludes the possibility of using the full length genome of type O FMDV.

Applicant's arguments have been carefully considered, but fail to persuade. Applicant's substantive arguments are directed to the following:

- Applicant argues that the amended claim is drawn to primers specifically for use in PCR amplification, defined on page 7 of the specification as being an oligonucleotide that is capable of acting as a point of initiation of nucleic acid synthesis or replication along a complementary strand when placed under conditions in which synthesis of a complementary strand is catalyzed by a polymerase. Applicant argues that the entire genome of FMDV cannot anticipate the instantly claimed primer oligonucleotide.
- In response to Applicant's argument, the genome of FMDV is a nucleotide sequence which is expected to be able to act as a point of initiation of nucleic acid synthesis or

replication along a complementary strand when placed under conditions in which synthesis of a complementary strand is catalyzed by a polymerase. It appears that Applicant is attempting to assign a length limitation on the term "oligonucleotide" in order to exclude the genome of FMDV as a primer, although no length limitation is found in the specification. The Office recognizes that the genome of FMDV is not what the art may consider to be a traditional-length primer oligonucleotide, the sequence is expected to function as a primer. Therefore, the sequence consists essentially of SEQ ID NO: 16, because, 1) it comprises SEQ ID NO: 16, 2) there is no length defined for oligonucleotides in the specification, and 3) it is expected to function as a PCR primer to detect FMDV.

- Applicant argues that it is art recognized that primers directed to nucleic acid amplification would be intolerant to substantial changes. Applicant points to several references filed September 17, 2009 as evidence of what was known in the art at the time of filing regarding PCR primers. Applicant asserts that the ordinary artisan can readily determine either empirically or by routine experimentation whether a modification of the sequence will still allow it to function as a PCR primer. In particular, Applicant points to Ausebel *et al.* (Exhibit C) which teaches that design of PCR primers is often fraught with failure, and that addition of even mismatched nucleotides at the 5' end of a primer sequence might still allow a given primer sequence to function in PCR.
- In response to this argument, it appears that Applicant is saying that primer design is unpredictable, thus the sequence disclosed by Beard cannot be presumed to be able to function as a PCR primer. (The Office also recognizes that Applicant does not

consider Beard's sequence to qualify as a PCR primer because of the length of the sequence.) On the other hand, Applicant appears to be saying that one of ordinary skill in the art can readily determine by experimentation whether a modification to SEQ ID NO: 16 (including nucleotides on either end of the intact SEQ ID NO: 16) will render the primer functional or non-functional. The Office acknowledges that primer design requires a certain level of skill, though not a level beyond the ordinary artisan. Applicant has not provided any evidence that Beard's sequence would not be capable of functioning as a PCR primer. General teachings about PCR design being fraught with failure does not mean that Beard's sequence will fail. Therefore, the rejection is maintained for reasons of record.

Conclusion

5. Claims 1-3 and 5-8 are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648